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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/713,669	11/14/2000	Jennifer L. Hillman	PF-0513-1 DIV	3645

7590

10/06/2003

LEGAL DEPARTMENT
INCYTE CORPORATION
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EXAMINER

PROUTY, REBECCA E

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 10/06/2003

64

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/713,669

Applicant(s)

Hillman et al.

Examiner

Rebecca Prouty

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 30, 2003
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-39 is/are pending in the application.
- 4a) Of the above, claim(s) 22-28 and 31-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20, 21, 29, and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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Claims 1-19 have been canceled. Claims 20-39 are still at issue and are present for examination.

Accordingly, claims 22-28 and 31-39 (corresponding to newly presented inventions) remain withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Applicants' arguments filed on 6-30-03, paper No. 13, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claims 20, 21, 29, and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 20 (upon which Claims 21, 29, and 30 depend) is indefinite in the recitation of "endooligopeptidase activity". There are two potential meanings of this term within the context of the instant invention. Applicants rely on page 16, lines 14-19 of the specification for support for this phrase. This portion of the specification states that HPRAP-1 has chemical and structural similarity with endooligopeptidase A related protein

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from *O. cuniculus*. The meaning of "chemical similarity" is taken to similarity in catalytic activity as no other potential meaning is apparent. Endooligopeptidase A related protein from *O. cuniculus* is known in the art to cleave bradykinin and neurotensin at specific bonds (see Hayashi et al.) thus one could interpret the phrase "endooligopeptidase activity" as reciting the ability of claimed polypeptides to specifically cleave bradykinin and neurotensin at the bonds cleaved by endooligopeptidase A related protein from *O. cuniculus*. Alternatively, one could interpret the phrase more generally to recite the ability of the claimed polypeptides to cleave any oligopeptide at an internal peptide bond. As such the claim is indefinite as the intended scope is unclear.

It is suggested that if applicants intent was the first of these meanings that the claim be amended to recite "endooligopeptidase A activity". Amendment as such would put all of the elected claims in condition for allowance as one would consider the disclosed species of SEQ ID NO:1 to be representative of a genus of variants having high similarity in **both** structure and function and one would know how to use all such variants for the cleavage of bradykinin and neurotensin. However, in view of the potential for this phrase to be

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interpreted much more broadly, the previous rejections of Claims 20 and 29 under 112, first paragraph for both lack of sufficient written description and lack of enablement for the entire scope of the claimed subject matter are maintained.

Claims 20 and 29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is explained in the previous Office Action.

Applicants argue that the current claims recite the genus of polypeptides claimed in structural terms such that one of skill in the art could identify many species that the claims encompass. While it acknowledged that the current claims differ from those held by the court to lack sufficient written description, as discussed in the written description guidelines the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination

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of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus, A representative number of species means that the species which are adequately described are representative of the entire genus. **Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.** Satisfactory disclosure of a representative number depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. For inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus. In the instant case the claimed genera of Claims 20 and 29 include species which are widely variant in function as they include polypeptides which will cleave any oligopeptide at any internal peptide bond. As such, neither the description of the structure and function of SEQ ID NO:1 (which cleaves bradykinin and neurotensin) nor the disclosure solely structural features present in all members of the genus is sufficient to be

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representative of the attributes and features of the entire genus.

Claims 20 and 29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polypeptides comprising SEQ ID NO:1, or a fragment of SEQ ID NO:1 having endooligopeptidase A activity or polypeptides having 95% identity to SEQ ID NO:1 and endooligopeptidase A activity, does not reasonably provide enablement for polypeptides comprising a fragment of SEQ ID NO:1 which can cleave any oligopeptide at any internal peptide bond or polypeptides having 95% identity to SEQ ID NO:1 which can cleave any oligopeptide at any internal peptide bond. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The rejection is explained in the previous Office Action.

While the examiner acknowledges that the skilled artisan could make and use fragments and variants as claimed having the same activity as SEQ ID NO:1 (endooligopeptidase A activity) it would require undue experimentation to make all such fragments and variants which would have the enormous number of additional activities encompassed within the generic phrase endooligopeptidase activity recited in the claim.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

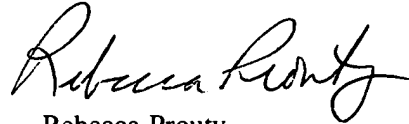
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca Prouty, Ph.D. whose telephone number is (703) 308-4000. The examiner can normally be reached on Monday-Friday from 8:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, can be reached at (703) 308-3804. The fax phone number for this Group is (703) 308-4242.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

A handwritten signature in cursive script, appearing to read "Rebecca Prouty".

Rebecca Prouty
Primary Examiner
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